

Significant Analysis for Rule Concerning
Pharmacists' Professional Responsibilities, WAC 246-863-095
& Pharmacies' Responsibilities, WAC 246-869-010

Background:

In 2004 media began to report on incidents occurring nationwide in which pharmacists have refused to dispense prescriptions for moral, religious and personal objections. In response, many state regulatory boards have enacted laws, regulations or adopted policies addressing a pharmacist's responsibilities. These laws, regulations and policies vary widely from requiring pharmacists to dispense all lawful prescribed drugs and devices; to allowing pharmacist to refuse for moral or religious objections; or provisions offering protections for consumer but remaining silent on pharmacists' rights to exercise their personal conscience.

In 2005 the Washington State Board of Pharmacy (Board) began to receive calls and emails inquiring to the Board's position on pharmacists' refusing to dispense drugs and devices for moral or ethical objections. Washington State pharmacy laws and rules were silent on this issue. The Board did not have a formal position; however, the Board stressed that public health and safety were primary. The Washington State Pharmacy Association (WSPA) informed the Board that it had formed an ad hoc committee to develop its position statement regarding this issue and asked to present the committee's findings to the Board.

Following the January 2006 presentation by WSPA, the Board voted to initiate the rule making process to examine a pharmacist's responsibilities to dispense lawful prescribed drugs or devices. The Board recognizes this is a very complex issue. But as a regulatory Board, they had concerns that requiring all lawful prescriptions to be filled would not adequately ensure public safety. The Board did consider it necessary to identify certain conduct as unprofessional as it relates to this issue; such as, placing additional barriers to patients' access to health care.

Until recently, the Board was unable to document the receipt of any complaints alleging a pharmacist refused to dispense to a patient a lawful prescribed drug or device for personal objection. However, the Board acknowledges that these incidents may go unreported or are reported to entities other than the Department of Health.

During rule development the Board determined that it may be necessary to address pharmacies' responsibilities to deliver lawful prescribed drugs and devices, as well. On November 13, 2006, the Board filed a *Preproposal Statement of Inquiry* to announce its intent to consider rules in this area and to provide an opportunity for stakeholder participation.

Briefly describe the proposed rule.

The Department of Health, Board of Pharmacy is proposing amendments to WAC 246-863-095 *Pharmacist's professional responsibilities*, and a new section, WAC 246-869-010 *Pharmacies' responsibilities* to promote patient safety and access to health care by emphasizing the professional responsibilities of pharmacists and pharmacies.

WAC 246-863-095

The proposed rule states that it is a pharmacist's primary responsibility to ensure patients receive safe and appropriate medication therapy.

The proposed rule:

- 1) Prohibits a pharmacist from delegating the decision to not dispense a lawful prescribed drug or devices to pharmacy support staff.
- 2) Provides grounds for discipline when a pharmacist, pharmacy intern, or pharmacy ancillary personnel engages in or permits the following conduct that is unprofessional.
 - (a) Destroy unfilled lawful prescription.
 - (b) Refuse to return unfilled lawful prescriptions.
 - (c) Violate a patient's privacy.
 - (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.
 - (e) Intimidate or harass a patient.

WAC 246-869-010

The proposed rule states that pharmacies have a duty to deliver/distribute lawful prescribed drugs and devices or provide a therapeutically equivalent drug or device to patients in a timely manner. The rule establishes requirements for a pharmacy to assure patients have access to lawfully prescribed and clinically safe medication therapy when a pharmacist cannot dispense.

The proposed rule:

- 1) Provides examples of circumstances when it may be appropriate for a pharmacy not to deliver/distribute lawful prescribed drugs, devices, or provide therapeutically equivalent drugs. The list is not inclusive but validates additional circumstances as substantially similar to those listed in the proposed rule. The circumstances listed include: national or state emergencies or guidelines affect the availability, usage or supply; potentially fraudulent prescriptions; lack of specialized equipment or expertise to safely produce, store or dispense a pharmaceutical; or when a pharmacy is not compensated for its usual and customary or contracted charge.
- 2) Requires pharmacies to provide patients with a timely alternative to appropriate therapy when the drug is not in stock because it is not customarily needed by the pharmacy's patients, or the drug is temporarily out-of-stock.

Proposed Rule Options for Out of Stock Drugs		
Contact prescriber for alternative drug therapy	Return prescription to patient	Refer patient to another pharmacy that will fill the prescription

- 3) Provides grounds for discipline when a pharmacy engages in or permits the following conduct that is unprofessional.
 - (a) Destroy unfilled lawful prescription.
 - (b) Refuse to return unfilled lawful prescriptions.
 - (c) Violate a patient's privacy.
 - (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.
 - (e) Intimidate or harass a patient.

Is a Significant Analysis required for this rule?

Yes.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 18.64.005 gives the Board of Pharmacy the authority to adopt rules for the dispensing, distribution, wholesaling and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare. The practice of pharmacy includes, but is not limited to, the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices [RCW 18.64.011 (11)].

RCW 18.130.050 grants the Board of Pharmacy the authority to adopt standards of professional conduct or practice.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rules are needed to minimize barriers to health care and to reduce risks for patients' health where there may be an emergent need for a prescribed drug or device. The people of Washington must know that they can get the medications they need without barriers to health care.

The proposed rules meet the goals and objectives of the statute by promoting patient safety and access to health care. The proposed rules provide clear expectations to assure patients have access to safe and appropriate medication therapy by eliminating barriers that would prevent patients from receiving timely access to their lawful prescribed or therapeutically equivalent drugs and devices.

The proposed rules meet the goals and objectives of the statute by clarifying the expectations for conduct and practice for pharmacists and pharmacies when presented with a lawful prescription. In addition, the rules adopt adequate grounds to discipline for failure to comply.

- A pharmacy or pharmacist may be disciplined for failing to ensure patients receive safe and appropriate medication therapy in a timely manner. However, a pharmacy or pharmacist is not subject to disciplinary action for refusing to dispense medications, so long as the pharmacy business takes steps to deliver the drug or device to the patient. Or when a medication is not in stock, the pharmacy is required to provide the patient with timely alternatives for appropriate therapy.

Exceptions:

A pharmacy may refuse to deliver a prescription when one of the exceptional circumstances in proposed rule WAC 246-869-010 subsection (1)(a) through (e) applies.

- A pharmacy or any person authorized to practice or assist in the practice of pharmacy may be disciplined for inappropriate/unprofessional conduct for destroying or refusing to return an unfilled lawful prescription; violating a patient's privacy; and for discriminating, intimidating or harassing a patient.

The adoption of policies and procedures can provide an alternative to rule making by establishing similar expectations for pharmacies and pharmacists to improve patients' access to safe and appropriate medication therapy. However, expectations established in policy do not provide an enforceable mechanism for noncompliance.

Note: Portions of the proposed amendments to WAC 246-863-095 do not require a significant analysis because they clarify existing language or adopt housekeeping changes.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The Board of Pharmacy has determined that the probable benefits of the proposed rules are greater than its probable costs to those that must comply. Costs of complying with the proposed rules must be balanced against significant medical and social cost of not receiving a time-dependent medication in a timely manner. Access to medication is a critical factor in an individual's health and the efficacy of some medications is directly related to receiving the medication within a specified time.

Healthcare providers stress the importance of taking medication as prescribed. For example, when a patient has an infection they are instructed to take the entire supply of antibiotics prescribed. Compliance or adherence refers to their ability to take their medications as prescribed. People who comply have better results in combating diseases than those who do not.

For example, human immunodeficiency virus (HIV) medications are highly time sensitive. An HIV patient must regularly take the HIV drugs prescribed to suppress the virus. The consequences of missing as few as three dosages can result in the virus mutating. If the virus mutates the current drug regimen is no longer effective, requiring new tests to determine what new combination of drugs may be effective. New drugs are usually less effective and more expensive. Given that the mutation is permanent, the ultimate consequence is that the patient's probability of long term survivability can be greatly diminished.

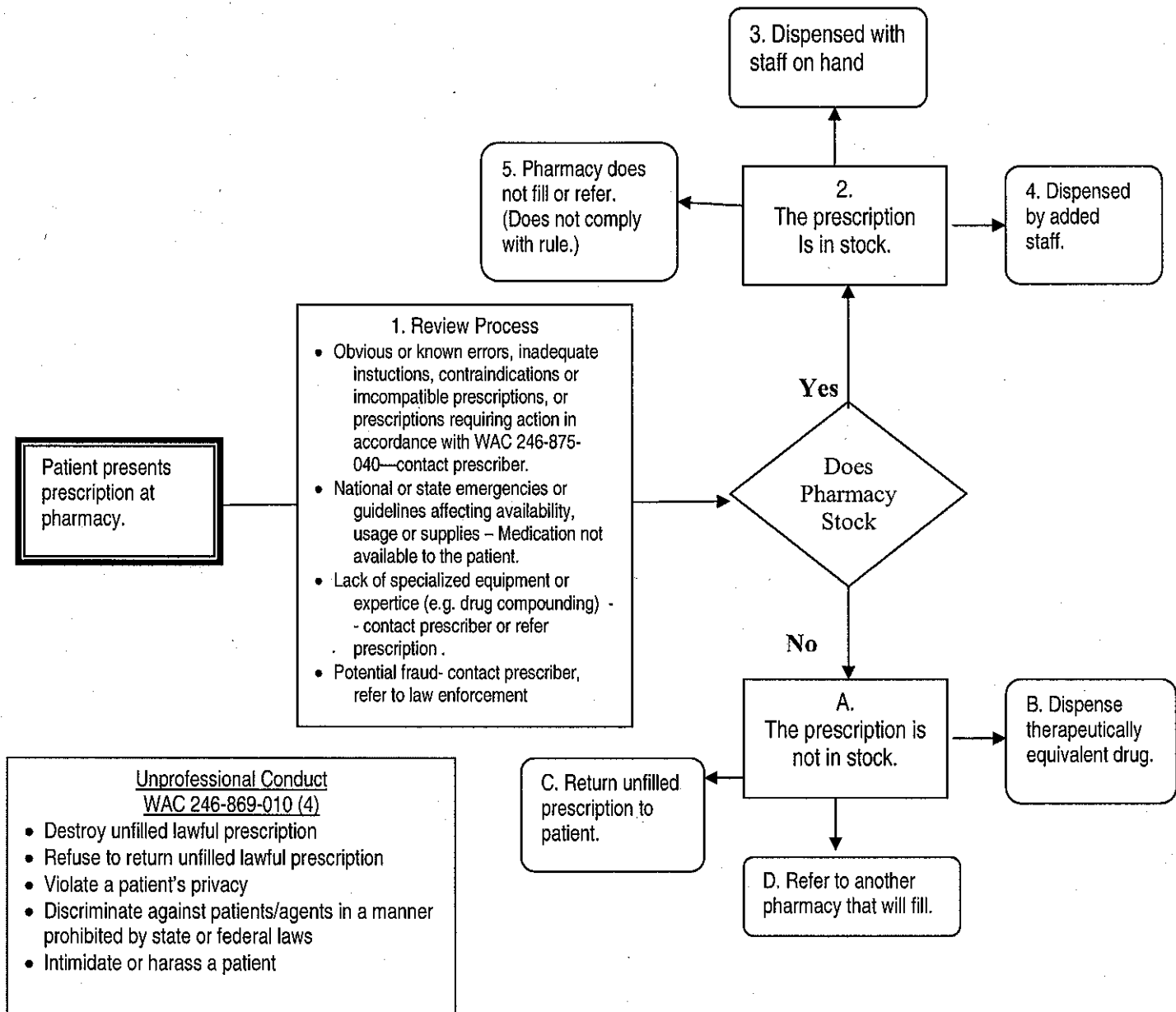
A similar case can be made for other time-dependent medications or devices such as insulin and diabetic syringes, emergency contraceptive pills and erectile dysfunction medications.

Probable Benefits of the Proposed Rule

- Increases pharmacies' and pharmacists' understanding of acceptable practice and behavior.
- Increases pharmacists' understanding of their primary responsibility to ensure patients receive safe and appropriate medication therapy.
- Increases pharmacies' understanding of its duty to deliver lawful prescribed drugs or therapeutically equivalent medication in a timely manner.
- Increase consumer confidence that they will have access to lawful prescribed drugs and devices.
- Increase consumer confidence that they will be treated appropriately without fear of discrimination or harassment
- Increases pharmacies' understanding of the expected outcomes when a pharmacist cannot dispense a prescription that is stocked by the pharmacy.
- Increase pharmacies' understanding of the acceptable alternative to providing medication therapy to patients when the medication is out-of-stock.

Probable Costs of the Proposed Rules

To analyze the probable costs of the proposed rule, we must first look at the processes a pharmacy must follow in order to comply. Many of these steps are considered customary practice in a pharmacy and will not impose additional costs.



In step 1 the pharmacist conducts a professional review of the prescription to determine the appropriateness of filling the prescription.

The first scenario, captured in steps 2-5, illustrates the expectations provided in subsection 1 of the proposed rule, WAC 246-869-010. Compliance cost is defined as a loss in current revenue, a loss in assets, or higher operating costs.

- Step 3, after a thorough review of the prescription, the pharmacy delivers with staff on-hand. There is no compliance cost.

- Step 4, after a thorough review of the prescription, the pharmacy complies with the proposed rule by having additional staff available to ensure the patient is delivered the appropriate medication therapy in situations when another pharmacist objects. The probable cost of additional staffing falls heavily on community pharmacies (small businesses) compared to corporate/chain pharmacies (large businesses) simply because of the availability of additional pharmacists. Corporate pharmacies tend to deliver/dispense larger volumes of prescriptions that support multiple pharmacists on duty at one time or overlapping shifts. Chain pharmacies often use “floaters”, staff that can assist at various locations as needed. On the other hand, community pharmacies tend to have one pharmacist per shift and may have difficulty in finding part-time/on-call pharmacists.
- Step 5, the pharmacy is not in compliance with the proposed rule and may be subject to disciplinary actions.

The second scenario, captured in steps A – D, illustrates the expectations provided in subsection 3 of the proposed rule WAC 246-869-010. In this scenario, the medication/device inventory is established in compliance with WAC 246-869-150.

- Step B – After a thorough review of the prescription, the pharmacist contacts the prescriber to address concerns, when appropriate. In this situation, a therapeutically equivalent product is identified and dispensed.
- Step C & D – After a thorough review of the prescription, the pharmacist contacts the prescriber, when appropriate. In this situation, the pharmacy has determined that it is unable to provide a timely alternative for appropriate therapy. By request of the patient, the prescription is returned (step C) or the prescription is transferred to a pharmacy of the patient’s/agent’s choice that will fill the prescription in a timely manner (step D).

Note: Possible costs may be incurred by pharmacies to maintain a representative assortment of drugs in order to meet the pharmaceutical needs of its patients; however, these costs are already present under existing rules. In addition, costs for medications are passed onto the consumer and pharmacies have an array of options to manage medication inventories:

- Returning soon to expire medication inventory to wholesalers/manufacturers.
- More frequent pharmaceutical deliveries – up to 6 days a week – requiring less inventory on hand.
- Pharmacies commonly borrow medications from each other when needed.

The Board of Pharmacy finds that any costs associated with proposed rules WAC 246-869-010 subsection (4) and WAC 246-863-093 subsections (2)(j) and (4), would be incurred only by those pharmacies or pharmacist who violate the act.

For specific costs, please refer to the *Small Economic Impact Statement*.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The Department of Health, Board of Pharmacy staff worked closely with constituents and the public to minimize the burden of this rule. Stakeholder rule writing workshops were held in Tumwater and Yakima. In the course of these and other efforts the rules went through numerous

drafts. The following alternative versions of these rules were rejected on the basis that they did not achieve the general goals and specific objectives stated previously.

A previous draft considered by the Board stated pharmacists shall dispense lawful prescribed drugs or devices on-site. This version of the rule did not take into account specialized pharmacy practices or possible state and federal emergencies which may affect the availability or supply of drugs and devices. In addition, it was thought to impose a disproportionate impact on small independent pharmacies possibly requiring increase staffing and stocking to comply with the rule.

Another draft alternative considered by the Board provided options for a pharmacist who cannot dispense a lawful prescription. The rule did not provide adequate protection for patient if a pharmacist denies the patient appropriate prescription drugs based on personal, religious or moral objection. The language did not address the pharmacies' responsibilities. Although this version was least burdensome for pharmacies and pharmacists, it did not achieve the goals and objective of the rule as previously stated.

The current proposal is consistent with the intent of the rule and the goals and objectives of the statutes. It clearly states a pharmacist's and pharmacy's responsibilities to ensure patients receive safe and appropriate medication therapy.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

These rules do not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

These rules do not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

These rules do not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other laws applicable to the same activity or subject matter.